

## **REMARKS**

### **STATUS OF THE CLAIMS**

Claims 1-30 were pending. Claims 1-7 and 27 have been canceled without prejudice or disclaimer. Accordingly, claims 8, 9 and 16 have been rewritten as independent claims and have also been amended as shown above to make explicit that x-ray image produced includes an image of the calibration phantom, to positively recite the step of generating a calibration curve and to positively recite that attenuation is also measured in at least one point of known density in the anatomical structure of the image. New claims 31-34 have been added as shown above. Support for the amendments to claims 8, 9 and 16 as well as new claims 31-34 can be found for example, on page 34, lines 10-19. The dependency of claim 28 has been corrected and claim 29 has been amended to incorporate the limitations of claim 30. Thus, claims 8-26 and 28-34 are pending as shown above.

### **SPECIFICATION**

Applicants note with appreciation the Examiner's reproduction of the suggested guidelines for arrangement of the specification. We note, however, that C.F.R. § 1.77(c) indicates that the sections are included only if applicable.

### **DRAWINGS**

The drawings have been objected to under 37 C.F.R. § 1.83(a). (Office Action, paragraphs 1-7). With respect to paragraphs 2-4 of the Office Action, Applicants submit herewith a new drawing showing all the features of claims 1, 6 and 7. Therefore, the objection has been obviated with regard to these features.

Turning to the objections set forth in paragraphs 5, 6 and 7 of the Office Action, Applicants submit that these objections are in error. Drawings are not required in an application for patent except in the case "where **necessary** for the understanding of the subject matter sought to be patented." See, 37 C.F.R. 1.81(a), emphasis added. Clearly, in the pending application, words describing how to generate density calibration curves; determining bone mineral density and make kits are more than sufficient to allow an understanding of the invention. Simply put, drawings are **not** necessary to an understanding of these claimed features. Indeed, because words have more than adequately explained the subject matter of these claims, drawings are clearly not required.

Therefore, the objections to drawings are either overcome by the submission of Fig. 10A-

C herewith or improper and should be withdrawn.

#### **CLAIM OBJECTIONS**

Claims 8, 9, 16, 19-24, 26 and 28-30 were objected to for a variety of informalities. (Office Action, paragraphs 8 to 16).

The objections to claims 19-24 as set forth in paragraph 12 of the Office Action has been obviated by cancellation of these claims.

Applicants appreciate the Examiner's suggested language set forth in paragraphs 9, 10 and 13-15 of the Office Action and have incorporated it herein. In particular, claim 8 has been rewritten to positively recite as a step of the method generating a calibration curve. Claim 9 has been amended to clarify the nature of the expected calibration curve. Claim 16 has been rewritten to clarify that x-ray image includes the calibration phantom. Claim 26 has been amended to proper dependent form. Claim 28 has been rewritten to make explicit that the x-ray is an x-ray image. Finally, the limitations of claim 30 have been incorporated into claim 29 to make explicit suitable treatments.

In view of the foregoing amendments and remarks, withdrawal of the objections to the claims is respectfully requested.

#### **REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 8 and 9 were rejected as allegedly indefinite for failing to recite essential steps. (Office Action, paragraph 18). Dependent claims 10-13, 25 and 26 were similarly rejected. In particular, it was alleged to be unclear how imaging of an anatomical structure results in producing of an x-ray image.

Claims 8 and 9 have been amended as shown above to make explicit that an x-ray image of an anatomical structure is produced and that the x-ray image comprises the calibration phantom. Thus, the rejection of claims 8, 9, 10-13, 25 and 26 as allegedly indefinite has been obviated.

In view of the foregoing amendments and remarks, withdrawal of the rejections under 35 U.S.C. § 112, second paragraph is respectfully requested.

#### **35 U.S.C. § 101, DOUBLE PATENTING**

Claims 1-30 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-30 of copending application serial no. 10/086,653. (Office Action, paragraph 20).

Applicants note that serial no. 10/086,653 is a continuation-in-part of the pending application and that, in view of the foregoing amendments, the claims are not longer conflicting.

**OBVIOUSNESS-TYPE DOUBLE PATENTING**

Claims 1-7 and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 32-43 and 47 of copending application serial no. 09/942,528 in view of U.S. Patent No. 5,335,260 (hereinafter "Arnold"). (Office Action, paragraph 24).

The cancellation of claims 1-7 and 27 has obviated this rejection.

**35 U.S.C. § 102**

A. CHIABRERA

Claims 1-4, 6, 7 and 27-30 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,917,877 (hereinafter "Chiabrera"). (Office Action, paragraph 24). It was maintained that Chiabrera discloses a calibration phantom "that projects free of bone tissue and is attached to the x-ray film holder or a detector system; and wherein the calibration phantom varies linearly and non-linearly along the length." (Office Action, paragraph 28).

Applicants traverse the rejection.

Claims 1-4, 6, 7 and 27 have been cancelled by amendment herein. In addition, claims 28-30 have been amended to depend from claim 8, which was not subject to this rejection. Accordingly, the rejection has been rendered moot and withdrawal thereof is requested.

B. SCHICK

Claims 8, 9, 11, 13, 14-16, 18-20, 23 and 24 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,852,647 (hereinafter "Schick"). (Office Action, paragraph 28). Citing Figure 4 and col 5, line 47 to col. 7, line 65, Schick is alleged to disclose a method comprising the steps of these claims. (Office Action, paragraph 39).

Applicants traverse the rejection.

Claim 8, 9, 11, 13, 14-16, 18-20, 23 and 24 are drawn to methods in which a calibration curve describing the relationship between measured attenuation and material thickness is generated. In addition, these claims also require that attenuation is measured within a region of the anatomical structure of the image.

Schick fails entirely to describe such calibration curves. Instead, the curves described in Schick are used to establish a relation between high-energy data and low-energy data of the same anatomical structure:

Using well known curve fitting techniques, a relationship is established between the high-energy image data and the low-energy image data. Preferably, a least-squares curve fit of the arrays is used ... (Schick, col. 5, lines 57-61)

Determining the relationship between high energy image data and low energy image data using curve fitting techniques is entirely unlike the claimed step of generating a calibration curve. Accordingly, Schick does not describe or suggest methods as set forth in claims 8, 9, 11, 13, 14-16, 18-20, 23 and 24.

Furthermore, with regard to the passage at col. 7, lines 34-65 cited in the Office Action, Applicants note that there is nothing in this passage that teaches or suggests methods as claimed. In this passage, Schick teaches a completely different method in which thickness of hard tissue above each pixel of bone is determined using a look-up table (or transmission-to-thickness function), which as Schick describes it is completely different than the calibration curves as claimed. Schick's function table is created by necessarily averaging "pixels in each step" of the wedge "to obtain an average pixel intensity for each step." (Schick, col. 7, lines 41-43). Subsequently, a curve (preferably a quadratic curve) is fitted to the averaged pixel intensity for each step. (Schick, col. 7, lines 43-45). In contrast, the claimed methods do not involve averaging pixel intensity in each step nor do the claimed methods involve fitting a curve to these pixel intensities.

There is also nothing in Schick that suggests using both measurements obtained from the image of the calibration phantom and from the image of the anatomical structure.

In sum, Schick does not describe or suggest the claimed calibration phantoms and, accordingly, does not anticipate pending claims 1-7 and 27.

### **35 U.S.C. § 103**

#### **A. CHIABRERA**

Claim 5 was rejected under 35 U.S.C. § 103(a) as allegedly obvious in view of Chiabrera. (Office Action, paragraph 5). Chiabrera was cited as above with regard to claims 1-4, 6, 7 and 27-30.

The cancellation of claim 5 by amendment herein has obviated this rejection and withdrawal thereof is respectfully requested.

B. SCHICK

Claims 10, 12, 17, 21, 22 and 25 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Schick. (Office Action, paragraph 36). Although it was acknowledged that Schick does not explicitly disclose the step of translating the calibration curve (function) describing thickness into a curve describing calcium concentration, it is alleged that it would have been obvious to modify Schick to arrive at these methods. (Office Action, paragraphs 41-43, citing col. 7, lines 49 to 50 in particular).

For the reasons detailed above, Schick does not teach or suggest generating a calibration curve as claimed. Rather, Schick describes generating a function by determining the average of pixel intensity in each step in a step wedge reference and by fitting a curve to the average pixel intensity. Therefore, Schick disclosure would not reasonable lead one of skill in the art to the claimed methods, in which a calibration curve is generated without averaging pixel intensity and without fitting a curve to these averages. Therefore, there is absolutely no suggestion in, or motivation from, Schick to arrive at any of the methods as claimed. Accordingly, withdrawal of rejection is in order.

**CONCLUSION**

Applicant submits that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: September 1, 2004

By: \_\_\_\_\_



Dahna S. Pasternak  
Attorney for Applicant  
Registration No. 41,411

ROBINS & PASTERNAK LLP  
1731 Embarcadero Road, Suite 230  
Palo Alto, CA 94303  
Tel.: (650) 493-3400  
Fax: (650) 493-3440

**AMENDMENTS TO THE DRAWINGS**

The attached sheets of drawings include new Figure 10. In particular, new Fig 10A-10C are attached.

Attachment: 1 New Sheet (FIG. 10A-C)